Billing Code 4160-90-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities:

Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project *"**Ambulatory Surgery Center Survey on Patient Safety Culture Database.**"*

This proposed information collection was previously published in the Federal Register on March 14th, 2018 and allowed 60 days for public comment. AHRQ received no substantive comments from members of the public. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by (insert date 30 days after date of publication).

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395-6974 (attention: AHRQ's desk officer) or by email at OIRA_submission@omb.eop.gov (attention: AHRQ's desk officer).

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

Ambulatory Surgery Center Survey on Patient Safety Culture Database

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, AHRQ invites the public to comment on this proposed information collection. Ambulatory surgery centers (ASCs) are a fast-growing health care setting, demonstrating tremendous growth both in the volume and complexity of procedures being performed. ASCs provide surgical services to patients who are not expected to need an inpatient stay following surgery. The Centers for Medicare and Medicaid Services (CMS) defines ASCs as distinct entities that operate exclusively to provide surgical services to patients who do not require hospitalization and are not expected to need to stay in a surgical facility longer than 24 hours.

How AHRQ's Mission and Directives Relate to ASCs. As described in its 1999 reauthorizing legislation, Congress directed the Agency for Healthcare Research and Quality (AHRQ) to enhance the quality, appropriateness, and effectiveness of health services, as well as access to such services, by establishing a broad base of scientific research and promoting clinical and health systems practice improvements. The legislation also directed AHRQ to "conduct and support research, evaluations, and training, support demonstration projects, research networks, and multidisciplinary centers, provide technical assistance, and disseminate information on health care and on systems for the delivery of such care, including activities with respect to health statistics, surveys, database development, and epidemiology." 42 U.S.C. 299a(a)(8). Shortly after Congress enacted this legislation, the Institute of Medicine (IOM) published "To Err is Human," a seminal report on medical errors that connects the dots between errors and workplace culture. In it, the IOM called for health care organizations to develop a "culture of safety" such that staffing and system processes are aligned to improve the reliability and safety

of patient care. This appeal for safety culture improvements directly relates to AHRQ's legislative directive and mission (i.e., "to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work within the U.S. Department of Health and Human Services and with other partners to make sure that the evidence is understood and used"). Given its legislatively-mandated role, AHRQ is uniquely positioned to support data collection and analyses that will help fuel ASC patient safety culture improvements. The expanding volume and scope of ASC services, the growing attention of federal regulators on patient safety within ASCs, and the resultant implications for public health has prompted AHRQ to present this application to the Office of Management and Budget (OMB). In this request, AHRQ seeks OMB approval to expand its Surveys on Patient Safety Culture™ (SOPS™) program by creating an ASC SOPS Database to capture and report on ASC SOPS data voluntarily-submitted by ASCs that have administered the ASC SOPS. The ASC SOPS Database is the newest database for the SOPS program and would be modeled after AHRQ's existing SOPS Databases for Hospitals, Medical Offices, Nursing Homes, and Community Pharmacies, which have all undergone OMB review and approval.

Background on ASC SOPS. This section provides context for this request to the OMB regarding the need for AHRQ's requested database. Factors include the continued ASC growth trajectory and increasing public attention on the quality of ASC care—particularly as it relates to patient safety culture.

Rapid ASC Growth. Medicare-certified ASCs have experienced impressive growth in the last 35 years—up from 239 facilities in 1983 to 5,316 in 2010. In recent years, Medicare ASCs have seen continued growth in both their number and scope, as illustrated by the annual average growth rate of 1.1 percent between 2010 to 2014. In 2015, CMS spent $4.1 billion for 3.4 million

fee-for service Medicare beneficiaries to receive care across 5,500 Medicare-certified ASCs. Research suggests that transitioning eligible surgical procedures from inpatient to ASC settings may yield significant and sustained Medicare cost savings.

Federal Attention on ASC Care Quality and Safety Culture. Concern about the quality of ASC care is not new. Following a 2008 Hepatitis C outbreak in Nevada blamed on poor ASC infection control practices, HHS's Office of the Secretary oversaw a $10 million program for state survey agencies to improve healthcare-associated infection reduction in ASCs. The Centers for Disease Control's (CDC) National Healthcare Safety Network (NHSN) subsequently expanded its surgical site infection (SSI) surveillance efforts to enable ASC data submission to accommodate state SSI reporting mandates. Through the Affordable Care Act of 2010, Congress also pursued ASC performance improvement by directing the HHS Secretary to implement an ASC-focused Medicare value-based purchasing (VBP) program.

The relationship between patient safety culture and the quality of ASC care has attracted more recent attention from policymakers and regulators. On the national level, the Joint Commission in early 2017 established within its ASC accreditation manual a new chapter on patient safety systems improvement, which includes strategies for "motivating staff to uphold a fair and just safety culture." CMS, meanwhile, published in November 2017 its Final Rule outlining the ASC Quality Reporting (ASCQR) Program, which ties quality and patient safety performance to reimbursement.

ASC SOPS Pilot. AHRQ developed and pilot tested the Ambulatory Surgery Center Survey on Patient Safety Culture (ASC SOPS) with OMB approval (OMB No. 0935-0216; approved 10/31/2013). The survey is designed to enable any ASC (regardless of type of procedures it performs) to assess their staff's perceptions about patient safety and quality assurance issues,

including what safety-related attitudes and behaviors are supported, rewarded, and expected. It includes 27 items that measure 8 composites of patient safety culture, as well as five individual items on near-miss documentation, overall rating on patient safety and communication in the procedure/surgery room. The pilot test was conducted in early 2014 in ASC facilities: (1) where patients have surgeries, procedures, and treatments and are not expected to need an inpatient stay, and (2) that have been certified and approved to participate in the CMS ASC program. Twenty-five percent of the pilot sites were affiliated with a hospital and 75% were not hospital-affiliated. Participants included 1,800 staff members from 59 ASCs—or approximately one percent of the total number of ASCs at that time.

AHRQ made the survey publicly available along with a Survey User's Guide, the pilot study results, and related toolkit materials on the AHRQ Ambulatory Surgery Center Survey on Patient Safety Culture Web page in April 2015.

The AHRQ ASC SOPS Database will consist of data from the AHRQ ASC patient safety culture survey. ASCs in the U.S. will be asked to voluntarily submit data from the survey to AHRQ. The ASC SOPS Database will be modeled after four other SOPS databases developed by AHRQ: Hospital SOPS [OMB NO. 0935-0162; last approved 10/18/2016]; Medical Office SOPS [OMB NO. 0935-0196; last approved 08/25/15]; Nursing Home SOPS [OMB NO. 0935-0195; last approved 09/30/15]; and Community Pharmacy SOPS [OMB NO. 0935-0218; last approved 06/26/17].

Rationale for the information collection. AHRQ sponsored the development of the ASC SOPS as a new survey in the suite of AHRQ Surveys on Patient Safety Culture. The database will support AHRQ's goals of promoting improvements in the quality and safety of health care in ASC settings. Like the survey and other toolkit materials, the database results will be made

publicly available on AHRQ's website. Technical assistance is provided by AHRQ through its contractor at no charge to ASCs to facilitate the use of these materials for ASC patient safety and quality improvement. Technical assistance will also be provided to support ASC data submission.

The goal of this project is to create the ASC SOPS Database. This database will:

1) Present results from ASCs that voluntarily submit their data;
2) Present trend data for ASCs that have submitted their data more than once;
3) Provide data to ASCs to facilitate internal assessment and learning in the patient safety improvement process; and
4) Provide supplemental information to help ASCs identify their strengths and areas with potential for improvement in patient safety culture.

This study is being conducted by AHRQ through its contractor, Westat, pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care services and with respect to health statistics, surveys, and database development.. 42 U.S.C 299a(a)(1) and (8).

Method of Collection

To achieve the goal of this project the following activities and data collections will be implemented:

1) **Eligibility and Registration Form** -- The point-of-contact (POC), often the manager of the ASC, completes a number of data submission steps and forms, beginning with completion of an online Eligibility and Registration Form. The purpose of this form is to collect basic demographic information about the ASC and initiate the registration process.

2) **ASC Site Information**– The purpose of the site level specifications, completed by the ASC manager, is to collect background characteristics of the ASC. This information will be used to analyze data collected with the ASC SOPS survey.
3) **Data Use Agreement** – The purpose of the data use agreement, completed by the ASC manager, is to state how data submitted by ASCs will be used and provides privacy assurances.
4) **Data Files Submission** –POCs upload their data file(s), using ASC survey data file specifications, to ensure that users submit standardized and consistent data in the way variables are named, coded, and formatted. The number of submissions to the database is likely to vary each year because ASCs do not administer the survey and submit data every year. Data submission is typically handled by one POC who is either an ASC administrative manager or a survey vendor who contracts with an ASC to collect and submit its data.

With the approval and addition of the ASC SOPS Database, data from the database will be used to produce three types of products:

1) An ASC SOPS Database Report that will be made publicly available on the AHRQ Web site (see, for example, another project in the SOPS suite, the Hospital User Database Report);
2) Individual ASC Survey Feedback Reports that are customized for each ASC that submits data to the database; and
3) Research data sets of individual-level and ASC-level data to enable researchers to conduct analyses. All data released in a data set are de-identified at the individual level and the ASC level.

ASCs will be invited to voluntarily submit their ASC SOPS survey data into the database. AHRQ's contractor, Westat, will then clean and aggregate the data to produce a PDF-formatted Database Report displaying averages, standard deviations, and percentile scores on the survey's 33 items and 8 patient safety culture dimensions. In addition, the report will also display results by respondent characteristics (e.g., staff position, tenure, and hours worked per week).

The Database Report will include a section on data limitations, emphasizing that the report does not reflect a representative sampling of the U.S. ASC population. Because participating ASCs will choose to voluntarily submit their data into the database and therefore are not a random or national sample of ASCs, estimates based on this self-selected group might be biased estimates. These limitations will be noted in the database report. We will recommend that users review the database results with these caveats in mind.

Each ASC that submits its data will receive a customized survey feedback report that presents their results alongside the aggregated results from other participating ASCs. If an ASC submits data more than once, its survey feedback report will also present trend data.

ASC users of the ASCs SOPS Survey, Database Reports, and Individual ASC Survey Feedback Reports can use these documents to:

- Raise staff awareness about patient safety;
- Diagnose and assess the current status of patient safety culture in their own ASC;
- Identify strengths and areas for patient safety culture improvement;
- Examine trends in patient safety culture change over time; and
- Evaluate the cultural impact of patient safety initiatives and intervention.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in the database. Given that this will be the first call for voluntary data submission, participation is initially expected to be modest. An estimated 100 ASC managers (i.e., POCs from ASCs) will complete the database submission steps and forms. Each POC will submit the following:

- Eligibility and registration form (completion is estimated to take about 5 minutes).
- Data use agreement (completion is estimated to take about 3 minutes).
- ASC Site Information Form (completion is estimated to take about 5 minutes).
- Survey data submission will take an average of one hour.

The total burden is estimated to be 121 hours.

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to submit their data. The cost burden is estimated to be $5,472.83

Exhibit 1. Estimated annualized burden hours

Form Name	Number of Respondents/POCs	Number of responses per POC	Hours per response	Total burden hours
Eligibility and Registration Form	100	1	5/60	8
Data Use Agreement	100	1	3/60	5
ASC Site Information Form	100	1	5/60	8
Data Files Submission	100	1	1	100
Total	NA	NA	NA	121

Exhibit 2. Estimated annualized cost burden

Form Name	Number of Respondents/POCs	Total burden hours	Average hourly wage rate*	Total cost burden
Eligibility and Registration Form	100	8	$45.23	$361.84
Data Use Agreement	100	5	$45.23	$226.15
ASC Site Information	100	8	$45.23	$361.84
Data Files Submission	100	100	$45.23	$4,523.00
Total	NA	121	$45.23	$5,472.83

*Based on the mean hourly wage for 100 ASC Administrative Services Managers (11-3011; $45.23) obtained from the May 2016 National Industry-Specific Occupational Employment and Wage Estimates: NAICS 621400 – Outpatient Care Centers (located at http://www.bls.gov/oes/current/naics4_621400.htm#11-0000).

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information

upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Francis D. Chesley, Jr.
Acting Deputy Director

[FR Doc. 2018-12767 Filed: 6/13/2018 8:45 am; Publication Date: 6/14/2018]